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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,660	09/15/2005	Jean-Louis Junien	102717.58257US	9879

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EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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11/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,660	Applicant(s) JUNIEN ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 14-18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 14-18, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed July 22, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejections)

1) Claims 12, 14-18, 20 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (Obesity Research 1998) in view of Chaput et al. (Biochemical and Biophysical Research Communications 2000).

Applicant's Arguments

Applicant asserts the combination of fenofibrate and metformin exhibit synergistic effects. Applicant argues Chaput et al. disclose fenofibrate reduces body weight gain in the Zucker rats but have no significant effect on body weight gain in *db/db* mice. The weight loss is dependent on the animal model employed. The claimed methods of treating obesity are not an obvious combination of two active ingredients disclosed in

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the art to treat obesity. Lee et al. and Chaput et al. do not teach that metformin and fenofibrate are useful for the same purpose. Accordingly the cited prior art does not disclose that both metformin and fenofibrate are individually useful for treating obesity, thus, it is not prima facie obvious to combine metformin and fenofibrate to treat obesity.

Examiner's Response

In regards to the "synergistic effects", see Examiner's previous response to the Declaration submitted by Jean-Louis Junien mailed February 23, 2009. The Examiner disagrees with Applicant's arguments and submits that Chaput et al. disclose fenofibrate reduces body weight in Zucker rats, which are known animal models for the treatment of diabetes (pages 445, col. 2, paragraph 4). Metformin is disclosed to induce weight loss in patients with diabetes. Thus the references do teach each of metformin and fenofibrate are useful for the same purpose of inducing weight loss in diabetic patients. Thus it is prima facie obvious to combine metformin and fenofibrate to treat obesity, especially in diabetic patients.

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2) Claims 12, 14-18, 20 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bonhomme et al. (US 6,372,790) in view of Lee et al. (Obesity Research 1998) and Chaput et al. (Biochemical and Biophysical Research Communications 2000).

Applicant's Arguments

Applicant argues Bonhomme et al. discloses treating type II non-insulin-dependent diabetes and not obesity. Chaput et al. disclose fenofibrate reduces body weight gain in the Zucker rats but have no significant effect on body weight gain in *db/db* mice. One would not look to Bonhomme et al. to arrive at the present invention because Bonhomme et al. disclose the treatment of non-insulin dependent diabetes and not obesity. Obesity and diabetes are distinct conditions and require different and specific treatments. Bonhomme is non-analogous art. Further there is not expectation of success using the compositions of Bonhomme et al. in the presently claimed methods of treating obesity because Bonhomme et al. treats diabetes.

Examiner's Response

Although the diseases are distinct conditions, one of skill in the art would recognize that both fenofibrate and metformin contribute to the weight loss of subjects with diabetes and would reasonably expect that the compositions of Bonhomme et al. would be effective for treating weight loss in individuals with diabetes, as well as diabetes, because the two active agents comprised therein induce weight loss. Further, as disclosed by Chaput et al., Zucker rats are used as animal models for diabetes, which gives further motivation as to why one of ordinary skill in the art would be motivated to use the compositions of Bonhomme et al. to treat obesity, especially in those patients having diabetes. Thus, it is prima facie obvious to treat obesity in diabetic patients with the compositions of Bonhomme et al. with reasonable expectation of success.

In regard to Bonhomme et al. being non-analogous art, Lee et al. disclose diabetes and weight loss and how metformin is used to induce weight loss in patients with diabetes. Bonhomme et al. disclose using metformin to treat diabetes, thus, making Bonhomme et al. analogous art to Lee et al.

Claims 12, 14-18, 20 and 21 are rejected.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612